CERTIFICATE OF I	MAILING BY "EXPRESS I	MAIL" (37 CFR 1.10)	Docket No. 31140B
Serial No. 10/051,662	Filing Date January 18, 2002	Examiner R. Cook	Group Art Unit
Invention: PREVENTIO	ON OF OVARIAN CANCER BY	ADMINISTRATION OF A VITA	AMIN D COMPOUND
I hereby certify that the	e following correspondence:		
	(Identify type	of correspondence)	
	the United States Postal Service pe addressed to: Commissioner March 31, 2004 (Date)	•	exandria, VA 22313-1450 on
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CERTIFICATE OF Applicant(s):	MAILING BY "EXPR	ESS MAIL" (37 CFR 1.10)	Docket No. 31140B
Serial No.	Filing Date	Examiner	Group Art Unit
10/051,662	January 18, 2002	R. Cook	1614
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	tion Disclosure Statement		
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804 %)		STATES PATENT	AND	TRADEMARK	OFFICE
Applicants:	Rodriguez et al.)		
Serial No.:	10/051662)	Examiner: R. Co	ook

Filed: January 18, 2002) Group Art Unit: 1614

For: Prevention of Ovarian Cancer by Administration of a Vitamin D Compound

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

To: Commissioner For Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §1.97(c), applicants submit this Supplemental Information

Disclosure Statement, submitting the art listed in the attached PTO Form 1449.

This Supplemental Information Disclosure Statement includes the following three categories of references: (1) two U.S. Patents issued in the name of Applicants, namely U.S. Patent Nos. 6,407,082 and 6,444,658; (2) Neer et al. U.S. Patent No. 4,833,125 ("the Neer patent"), as well as documents from Applicants' related PCT application, PCT/US98/11737; and (3) the full Need reference (applicants previously provided a copy of the full reference with their amendment dated February 5, 2004, but with an Information Disclosure Statement).

A. The Neer Patent

The International Preliminary Examination Report for Applicants' PCT application PCT/US98/11737 cites the Neer patent. A copy of the Report is included herewith. The report identifies col. 7, lines 16-19 as pertinent to one claim in the PCT application. The cited portion of the Neer patent reads:

A typical pharmaceutical mixed composition of the invention would contain PTHF in combination with a hydroxylated vitamin D compound or calcium in a form suitable for use as a dietary calcium supplement.

The Neer patent was cited only against claim 25 in the pending PCT application. The other claims were found to have novelty and inventive step over the references cited. (See International Preliminary Examination Report, V.1.).

Claim 25 of application PCT/US98/11737 reads as follows:

25. A pharmaceutical composition for inhibiting the conversion of non-neoplastic ovarian epithelial cells to neoplastic cells comprising a *Vitamin D compound* and a *hormone product*.

(See PCT/US98/11737 submitted herewith). Thus, claim 25 was directed to a combination of a Vitamin D compound and a hormone product. The International examining entity cited the Neer reference as showing that claim 25 lacked novelty. (See International Preliminary Examination Report at V.1.). Neer combines a parathyroid hormone, PTHF, with either Vitamin D or calcium.

However, the International Application also included claims directed to the combination of Vitamin D and a progestin product, specifically claims 26-34. Claim 26 is exemplary:

26. The pharmaceutical composition of claim 25 wherein said hormone is a *progestin product*.

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With respect to the claims directed to the combination of Vitamin D and a progestin product, the International examining entity found both novelty and inventive step. (See International Preliminary Examination Report at V.1.). Neer does not disclose or suggest any use of a progestin product.

In the pending U.S. Application Serial No. 10/051,662 at issue here, claims 35 and 45 were the only two claims that broadly recited "a hormone product." However, those claims are now amended to be are more narrowly drawn to "a progestin product."

The Supplemental Information Disclosure Statement also includes the Initial International Search Report in connection with the same application PCT/US98/11737.

B. The Full Need Reference

In the August 7, 2003 Office Action, the Examiner brought to the Applicants' attention the abstract of the Need et al. reference. Applicants submitted a copy of the full Need reference with their prior amendment of February 9, 2004. As explained in the Applicants' amendment filed February 9, 2004, the Need reference does not teach or provide any motivation to make: (1) a single unit dosage of Vitamin D and progestin; (2) a contraceptively effective regimen having both Vitamin D and a progestin; or (3) any dosages for administration to postmenopausal women in specific dosages different from what Need used.

Serial No.: 10/051,662 Our File No. 31140-B

Please charge the fee required by 37 CFR §1.97(c)(2) and §1.17(p), and any additional fees, to Deposit Account No. 18-1942.

Respectfully submitted,

Raymond N. Nimrod ROPER & QUIGG Reg. No. 31,987

200 South Michigan Avenue

Suite 1000

Chicago, Illinois 60604 Tel (312) 408-0855

March 31, 2004

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Sheet 1

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known		
Application Number	10/051,662	
Filing Date	01/18/02	
First Named Inventor	RODRIGUEZ	
Art Unit	1614	
Examiner Name	R. Cook	
Attorney Docket Number	31140B	

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	-	Number-Kind Code ² (# known)	05 22 1000	Neer et al.	Col. 7. lines 16-19
	D1	^{US-} 4,833,125	05-23-1989		Coi. 7. lines 10-13
	D2	^{US-} 6,407,082 B1	06-18-2002	Rodriguez et al.	
	D3	us- 6,444,658 B1	09-03-2002	Rodriguez et al.	
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 FOREIGN PATENT DOCUMENTS						
Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	1 7-6	
İ	Country Code ^{3 "} Number ^{4 "} Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	L	
E1	PCT Int'l App.	12-17-1998	Rodriguez et al		<u></u>	
	WO98/56389				<u> </u>	
 E2	Int'l Prel. Ex. Rpt.	09-09-1999	Rodriguez et al		L	
	PCT/US98/11737				<u> </u>	
 E3	Int'l Search Rpt.	09-09-1999	Rodriguez et al		L	
	PCT/US98/11737					

Examiner		Date	
	·	Considered	
Signature		Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

PTO/SB/08B (08-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

MAR 3 1 2004 no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 14 **Application Number** 10/051,662 Filing Date INFORMATION DISCLOSURE 01/18/02 STATEMENT BY APPLICANT **First Named Inventor** RODRIGUEZ Art Unit 1614 (Use as many sheets as necessary) **Examiner Name** R. Cook Attorney Docket Number 31140B

Sheet

2

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	F1	Need et al., "Comparison of calcium, calcitrol, ovarian hormones and nandrolone in the treatment of osteoporosis." Maturitas 8:275-280 (1986).	
<u></u>			1

Date Examiner Considered Signature

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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